Irvine Scientific JAN 1 7 2001 October 11, 2000

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

Irvine Scientific Sales Co., Inc.
2511 Daimler Street
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Contact: Wendell Lee, Pharm. D.

Date Submitted: October 11, 2000

Device Identification:

Trade Name:	Complete HTF Medium with SSS
Common Name:	Complete HTF
Classification Name:	Reproductive Media (21 CFR 884.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335
HTF Liquid (K983584)
P-1 (K983589)
Serum Substitute Supplement (K983579)

Description:

Complete HTF Medium with SSS is a media intended for use in assisted reproductive technology procedures. It has been formulated to mimic the composition of the fluid found in human fallopian tubes. Complete HTF Medium with SSS uses a sodium bicarbonate buffering system and is appropriate for those procedures requiring the use of a carbon dioxide atmosphere during incubation.

Intended Use:

Complete HTF Medium with SSS is intended for use in vitro fertilization and the culture of human embryos.

Technological Characteristics:

Complete HTF Medium with SSS is primarily used as a medium to support in vitro fertilization and post fertilization embryo growth. The embryo is allowed to grow in the medium until the desired state of development is reached, usually three days. (cHTF/SSS) utilizes a sodium bicarbonate buffer system that allows it to be used in CO_2 incubators.

Performance Data:

Complete HTF Medium with SSS is assayed by mouse embryo assay prior to its release to market. This assay assures that the product will support embryonic growth and that no toxic components are present. The equivalent of Complete HTF Medium with SSS (HTF supplemented with 10% SSS) has been used in a variety of clinical settings for the same intended use for a number of years and has become the standard medium used for the fertilization and growth of human gametes and embryos.

Additional Information:

Mouse embryo, endotoxin and sterility testing will be performed as a condition of release for this product. Results of all release assays performed will be indicated on the labeling and reported on a lot-specific certificate of analysis.

Conclusion:

The conclusion from performance testing as well as a review of the historical information contained in professional literature shows that Complete HTF Medium with SSS is suitable for the intended use and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 in addition to showing substantial equivalence to other 510(k) cleared Irvine Scientific products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2001

Wendell Lee, Pharm. D.
Vice President, Quality Systems and Regulatory Affairs
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705-5588

Re: K003278
Complete Human Tubal Fluid (HTF) with Serum Substitute Supplement
Dated: October 11, 2000
Received: October 19, 2000
Regulatory Class: II
21 CFR§884.6180/Procode: 85 MQL

Dear Dr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K003278

Device Name: Complete HTF Medium with SSS

Indications for Use:

Complete HTF Medium with SSS is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. The medium is able to support in vitro fertilization and post fertilization embryo growth in an incubator by mimicking substances found in the human female reproductive system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003278

Prescription Use ✓
(Per 21 CFR 801.109)